General

Guideline Title

2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ.

Bibliographic Source(s)

Wright TC Jr, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D, 2006 American Society for Colposcopy and Cervical Pathology-sponsored Consensus. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. Am J Obstet Gynecol. 2007 Oct;197(4):340-5. [55 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Wright TC Jr, Cox JT, Massad LS, Carlson J, Twiggs LB, Wilkinson EJ. 2001 consensus guidelines for the management of women with cervical intraepithelial neoplasia. Am J Obstet Gynecol 2003 Jul;189(1):295-304.

The guideline was reaffirmed for currency by the developer in 2011.

Recommendations

Major Recommendations

The ratings of the strength of recommendation (A-E), the quality of the evidence (I-III), and terminology used by the consensus conference (recommended, preferred, acceptable, unacceptable) are defined at the end of the Major Recommendations.

Note from the American Society for Colposcopy and Cervical Pathology (ASCCP): The management of low-grade cervical intraepithelial neoplasia (CIN) grade 1 has been modified significantly since 2001. Previously, management depended on whether colposcopy was satisfactory and treatment using ablative or excisional was acceptable for all women with CIN 1. In the new guidelines, cytological follow-up is the only recommended management option for women with CIN 1 who have low-grade referral cervical cytology, regardless of whether the colposcopic examination is satisfactory. Treatment is particularly discouraged in adolescents. The basic management of women in the general population with CIN 2,3 underwent only minor modifications, but options for the conservative management of adolescents with CIN 2,3 have been expanded. Moreover, management recommendations for women with biopsy-confirmed adenocarcinoma in situ are now included.

When human papillomavirus deoxyribonucleic acid (HPV DNA) testing is recommended, it applies only to testing for "high-risk" oncogenic HPV types using a validated assay.

Recommended Management of Women with Cervical Intraepithelial Neoplasia 1 (CIN 1)

CIN 1 preceded by atypical squamous cells of undetermined significance (ASC-US); atypical squamous cells cannot exclude high-grade squamous intraepithelial lesion (HSIL) (ASC-H), or cytological low-grade squamous intraepithelial lesion (LSIL) cytology.

The recommended management of women with a histological diagnosis of CIN 1 preceded by an ASC-US, ASC-H, or LSIL cytology is follow-up with either HPV DNA testing every 12 months or repeat cervical cytology every 6 to 12 months. (BII) If the HPV DNA test is positive or if repeat cytology is reported as ASC-US or greater, colposcopy is recommended. If the HPV test is negative or 2 consecutive repeat cytology tests are "negative for intraepithelial lesion or malignancy," return to routine cytological screening is recommended. (AII)

If CIN 1 persists for at least two years, either continued follow-up or treatment is acceptable. (CII) If treatment is selected and the colposcopic examination is satisfactory, either excision or ablation is acceptable. (AI) A diagnostic excisional procedure is recommended if the colposcopic examination is unsatisfactory, the endocervical sampling contains CIN, or the patient has been previously treated. (AIII)

Treatment modality should be determined by the judgment of the clinician and should be guided by experience, resources, and clinical value for the specific patient. (A1) In patients with CIN 1 and an unsatisfactory colposcopic examination, ablative procedures are unacceptable. (EI) Podophyllin- or podophyllin-related products are unacceptable for use in the vagina or on the cervix. (EII) Hysterectomy as the primary and principal treatment for histological diagnosed CIN 1 is unacceptable. (EII)

CIN 1 Preceded by HSIL or AGC-NOS Cytology

Either a diagnostic excisional procedure or observation with colposcopy and cytology at 6 month intervals for 1 year is acceptable for women with a histological diagnosis of CIN 1 preceded by HSIL or atypical glandular cells–not otherwise specified (AGC-NOS) cytology, provided in the latter case that the colposcopic examination is satisfactory and endocervical sampling is negative. (BIII) In this circumstance it is also acceptable to review the cytological, histological, and colposcopic findings; if the review yields a revised interpretation, management should follow guidelines for the revised interpretation. (BII)

If observation with cytology and colposcopy is elected, a diagnostic excisional procedure is recommended for women with repeat HSIL or AGC-NOS cytological results at either the 6- or 12-month visit. (CIII) After 1 year of observation, women with 2 consecutive "negative for intraepithelial lesion or malignancy" results can return to routine cytological screening. A diagnostic excisional procedure is recommended for women with CIN 1 preceded by a HSIL or AGC-NOS cytology in whom the colposcopic examination is unsatisfactory, except in special populations (e.g., pregnant women). (BII)

CIN 1 in Special Populations

Adolescent Women

Follow-up with annual cytological assessment is recommended for adolescents with CIN 1. (AII) At the 12 month follow-up, only adolescents with HSIL or greater on the repeat cytology should be referred to colposcopy. At the 24 month follow-up, those with an ASC-US or greater result should be referred to colposcopy. (AII) Follow-up with HPV DNA testing is unacceptable. (EII)

Pregnant Women

The recommended management of pregnant women with a histological diagnosis of CIN 1 is follow-up without treatment. (BII) Treatment of pregnant women for CIN 1 is unacceptable. (EII)

Recommended Management of Women with CIN 2, 3

Initial Management

Both excision and ablation are acceptable treatment modalities for women with a histological diagnosis of CIN 2,3 and satisfactory colposcopy, except in special circumstances (see following text). (AI) A diagnostic excisional procedure is recommended for women with recurrent CIN 2,3. (AII) Ablation is unacceptable and a diagnostic excisional procedure is recommended for women with a histological diagnosis CIN 2,3 and unsatisfactory colposcopy (AII). Observation of CIN 2,3 with sequential cytology and colposcopy is unacceptable, except in special circumstances (see following text). (EII) Hysterectomy is unacceptable as primary therapy for CIN 2,3. (EII)

Follow-up after Treatment

Acceptable post-treatment management options for women with CIN 2,3 include HPV DNA testing at 6 to 12 months. (BII) Follow-up using either cytology alone or a combination of cytology and colposcopy at 6 month intervals is also acceptable. (BII) Colposcopy with endocervical sampling is recommended for women who are HPV DNA positive or have a repeat cytology result of ASC-US or greater. (BII) If the HPV DNA test is negative or if 2 consecutive repeat cytology tests are "negative for intraepithelial lesion or malignancy," routine screening for at least 20 years

commencing at 12 months is recommended. (AI) Repeat treatment or hysterectomy based on a positive HPV DNA test is unacceptable. (EII)

If CIN 2,3 is identified at the margins of a diagnostic excisional procedure or in an endocervical sample obtained immediately after the procedure, reassessment using cytology with endocervical sampling at 4 to 6 months after treatment is preferred. (BII) Performing a repeat diagnostic excisional procedure is acceptable. (CIII) Hysterectomy is acceptable if a repeat diagnostic procedure is not feasible.

A repeat diagnostic excision or hysterectomy is acceptable for women with a histological diagnosis of recurrent or persistent CIN 2,3. (BII)

CIN 2,3 in Special Populations

Adolescent and Young Women

For adolescents and young women with a histological diagnosis of CIN 2,3 not otherwise specified, either treatment or observation for up to 24 months using both colposcopy and cytology at 6 month intervals is acceptable, provided colposcopy is satisfactory. (BIII)

When a histological diagnosis of CIN 2 is specified, observation is preferred but treatment is acceptable. When a histological diagnosis of CIN 3 is specified or when colposcopy is unsatisfactory, treatment is recommended. (BIII)

If the colposcopic appearance of the lesion worsens or if HSIL cytology or a high-grade colposcopic lesion persists for 1 year, repeat biopsy is recommended. (BIII) After 2 consecutive "negative for intraepithelial lesion or malignancy" results, adolescents and young women with normal colposcopy can return to routine cytological screening. (BII)

Treatment is recommended if CIN 3 is subsequently identified or if CIN 2,3 persists for 24 months. (BII)

Pregnant Women

In the absence of invasive disease or advanced pregnancy, additional colposcopic and cytological examinations are acceptable in pregnant women with a histological diagnosis of CIN 2,3 at intervals no more frequent than every 12 weeks. (BII) Repeat biopsy is recommended only if the appearance of the lesion worsens or if cytology suggests invasive cancer. (BII) Deferring reevaluation until at least 6 weeks postpartum is acceptable. (BII) A diagnostic excisional procedure is recommended only if invasion is suspected. (BII) Unless invasive cancer is identified, treatment is unacceptable. (EII) Reevaluation with cytology and colposcopy is recommended no sooner than 6 weeks postpartum. (CIII)

Recommended Management of Women with Adenocarcinoma in Situ (AIS)

Hysterectomy is preferred for women who have completed child-bearing and have a histological diagnosis of AIS on a specimen from a diagnostic excisional procedure. (CIII) Conservative management is acceptable if future fertility is desired. (AII) If conservative management is planned and the margins of the specimen are involved or endocervical sampling obtained at the time of excision contains CIN or AIS, reexcision to increase the likelihood of complete excision is preferred. Reevaluation at 6 months using a combination of cervical cytology, HPV DNA testing, and colposcopy with endocervical sampling is acceptable in this circumstance. Long-term follow-up is recommended for women who do not undergo hysterectomy. (CIII)

Definitions:

Rating the Recommendations

Strength of Recommendation*

Good evidence for efficacy and substantial clinical benefit support recommendations for use.
Moderate evidence for efficacy or only limited clinical benefit supports recommendation for use.
Evidence for efficacy is insufficient to support a recommendation for or against use, but recommendations may be made on other grounds.
Moderate evidence for lack of efficacy or for adverse outcome supports a recommendation against use.
Good evidence for lack of efficacy or for adverse outcome supports a recommendation against use.

Quality of Evidence*

Evidence from at least one randomized controlled trial
Evidence from at least one clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), or from multiple time-series studies, or dramatic results from uncontrolled experiments
Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

Terminology**

Recommended: Good data to support use when only one option is available.

Preferred: Option is the best (or one of the best) when there are multiple other options.

Acceptable: One of multiple options when either there are data indicating that another approach is superior or when there are no data to favor any single option.

Unacceptable: Good data against use.

*Modified from Gross PA, Barrett TL, Dellinger EP, et al. Purpose of quality standards for infectious diseases. Infectious Diseases Society of America. Clin Infect Dis 1994;18:421 and Kish MA. Guide to development of practice guidelines. Clin Infect Dis 2001;32:8511.

**The assignment of these terms represents an opinion ratified by the Consensus Conference.

Clinical Algorithm(s)

The following algorithms are available in Portable Document Format (PDF) on the American Society of Colposcopy and Cervical Pathology Web site :

- Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia Grade 1 (CIN 1) Preceded by ASC-US, ASC-H. or LSIL Cytology
- Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia Grade 1 (CIN 1) Preceded by HSIL or AGC-NOS Cytology
- Management of Adolescent Women (20 Years and Younger) with a Histological Diagnosis of Cervical Intraepithelial Neoplasia Grade 1 (CIN 1)
- Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia (CIN 2,3)
- Management of Adolescent and Young Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia-Grade 2,3 (CIN 2,3)
- Management of Women with Adenocarcinoma in Situ (AIS)-Diagnosed from a Diagnostic Excisional Procedure

Scope

Disease/Condition(s)

- Cervical intraepithelial neoplasia (CIN 1) (low-grade lesions) or CIN 2,3 (high-grade precursor lesions)
- Cervical adenocarcinoma in situ (AIS), a human papillomavirus (HPV)-associated precursor

Guideline Category

Management

Prevention

Risk Assessment

Screening

Clinical Specialty

Family Practice

Obstetrics and Gynecology

Oncology

Pathology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Plans

Managed Care Organizations

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To provide consensus guidelines for the management of women with histologically confirmed cervical intraepithelial neoplasia (CIN) and adenocarcinoma in situ (AIS) that can act as a precursor to invasive cervical cancer
To update the 2001 consensus guidelines for the management of women with cervical intraepithelial neoplasia

Target Population

Women with cervical intraepithelial neoplasia (CIN) or adenocarcinoma in situ (AIS)

Interventions and Practices Considered

Management of Women with Cervical Intraepithelial Neoplasia 1 (CIN 1)

Preceded by Atypical Squamous Cells of Undetermined Significance (ASC-US)

Human papillomavirus deoxyribonucleic acid (HPV DNA) testing
Repeat cervical cytology
Colposcopy
Excision or ablation

Preceded by High-Grade Squamous Intraepithelial Lesion (HSIL) or Atypical Glandular Cells Not Otherwise Specified (AGC-NOS)

Diagnostic excisional procedure
Colposcopy and cytology

Management of Women with Cervical Intraepithelial Neoplasia 2, 3 (CIN 2,3)

Initial Management

Excision and ablation
Diagnostic excisional procedure (alone, if recurrent CIN 2,3)

Follow-up after Treatment

HPV DNA testing
Cytology
Colposcopy and cytology
Colposcopy with endocervical sampling
Repeat diagnostic excisional procedure
Hysterectomy (only if recurrent or persistent CIN 2,3)

Management of Women with Cervical Adenocarcinoma in Situ (AIS)

Diagnostic excisional procedure with margin status
Hysterectomy (preferred)

Women Who Wish to Maintain Fertility

Diagnostic excisional procedure with margin status
Reexcision
Reevaluation using combination of cervical cytology, HPV DNA testing, and colposcopy with endocervical sampling

Note: See the "Major Recommendations" field for the interventions specific to a special population, such as adolescent or pregnant women.

Major Outcomes Considered

Sensitivity and specificity of testing
Rate of invasive cervical cancer after treatment
Rate of recurrent/persistent cervical intraepithelial neoplasia (CIN)
Rate of recurrent/persistent cervical adenocarcinoma in situ (AIS)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Original 2001 Guideline

The guideline developer performed searches of the U.S. Library of Medicine's MEDLINE database for English-language articles published between 1988 and 2001.

2006 Update

The process used to develop the 2006 guidelines was similar to that for the 2001 guidelines. Working groups initially defined questions and performed literature reviews of articles published since 2000.

2011 Currency Review Process

The American Society for Colposcopy and Cervical Pathology (ASCCP) regularly reviews current evidence to support meetings where a determination is made whether to maintain or update its guidelines. Since publication of the 2006 guidelines, three (3) separate literature searches have been performed; 1) 2008 search of Medline/PubMed supporting the Practice Improvement in Cervical Screening and Management (PICSM) 2009 Adolescent Symposium, 2) 2009-2010 search of Medline/PubMed and Cochrane for the American Cancer Society (ACS)/ASCCP/American Society for Clinical Pathology (ASCP) Cervical Cancer Screening Guidelines (Nov. 2011) , and 3) 2011 search of Medline/PubMed supporting the March 2012 ASCCP/CAP Conference on Terminology .

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence*

Evidence from at least one randomized controlled trial
Evidence from at least one clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), or from multiple time-series studies, or dramatic results from uncontrolled experiments
Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

*Modified from Gross PA, Barrett TL, Dellinger EP, et al. Purpose of quality standards for infectious diseases. Infectious Diseases Society of America. Clin Infect Dis 1994;18:421 and Kish MA. Guide to development of practice guidelines. Clin Infect Dis 2001;32:8511.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

Description of Methods Used to Formulate the Recommendations

From September 18 through 19, 2006, the American Society for Colposcopy and Cervical Pathology (ASCCP) hosted a consensus conference in Bethesda, MD, to revise the 2001 evidence-based guidelines for the management of women with cervical intraepithelial neoplasia (CIN) and include new information on how to manage women with cervical adenocarcinoma in situ (AIS).To ensure that the guidelines reflect the needs of the diverse array of clinicians providing cervical cancer screening, the consensus conference included a group of 146 experts representing 29 organizations and professional societies. Input from the professional community at large was obtained using an Internet-based bulletin board.

At the consensus conference, guidelines with supporting evidence were presented and underwent discussion, revision, and approval.

2011 Currency Review Process

See the "Description of Methods Used to Collect/Select the Evidence" field for background. In preparing for all three meetings, review committees composed of stakeholders from multiple organizations reaffirmed the currency of the 2006 ASCCP guidelines.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation*

Good evidence for efficacy and substantial clinical benefit support recommendations for use.
Moderate evidence for efficacy or only limited clinical benefit supports recommendation for use.

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**The assignment of these terms represents an opinion ratified by vote by the Consensus Conference.

Cost Analysis

Published cost analyses were reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Draft guidelines were posted on the American Society for Colposcopy and Cervical Pathology (ASCCP) Internet Web site bulletin boards for public comment. At the consensus conference, guidelines with supporting evidence were presented and underwent discussion, revision, and approval.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of women with cervical intraepithelial neoplasia (CIN) or adenocarcinoma in situ (AIS)

Potential Harms

Cold-knife conization increases a woman's risk of future preterm labor, a low birthweight infant, and a cesarean section.

Loop excision procedure or laser conization increases the risk of future preterm labor, a low birthweight infant, and premature rupture of membranes.
Studies have suggested that there is an increased recurrence rate of adenocarcinoma in situ (AIS) as well as an increase in positive margins when a loop excision procedure as opposed to cold-knife conization is used.
Ablative methods may have an adverse effect on future pregnancies.
Treatment of cervical intraepithelial neoplasia (CIN) during pregnancy is associated with complications and a high rate of recurrence or persistence.

Qualifying Statements

Qualifying Statements

It is important to recognize that these guidelines should never substitute for clinical judgment. Clinical judgment should always be used when applying a guideline to an individual patient because it is impossible to develop guidelines that apply to all situations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Wright TC Jr, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D, 2006 American Society for Colposcopy and Cervical

Pathology-sponsored Consensus. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. Am J Obstet Gynecol. 2007 Oct;197(4):340-5. [55 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2003 Jul (revised 2007 Oct; reaffirmed 2011)

Guideline Developer(s)

American Society for Colposcopy and Cervical Pathology - Medical Specialty Society

Guideline Developer Comment

Participating organizations include: American Academy of Family Physicians; American Cancer Society; American College Health Association; American College of Obstetricians and Gynecologists; American Social Health Association; American Society for Clinical Pathology; American Society for Colposcopy and Cervical Pathology; American Society of Cytopathology; Association of Reproductive Health Professionals; Centers for Disease Control and Prevention, Division of Viral and Rickettsial Disease; Centers for Disease Control and Prevention, Division of Cancer Prevention and Control; Centers for Disease Control and Prevention, Division of Laboratory Systems; Centers for Medicaid and Medicare Services; College of American Pathologists; Food and Drug Administration; International Academy of Cytology; International Federation for Cervical Pathology and Colposcopy; International Federation of Gynecology and Obstetrics; International Gynecologic Cancer Society; International Society of Gynecological Pathologists; National Cancer Institute; National Association of Nurse Practitioners in Women's Health; Papanicolaou Society of Cytopathology; Pan American Health Organization; Planned Parenthood Federation of America; Society of Canadian Colposcopists; Society of Gynecologic Oncologists; Society of Gynecologic Oncologists of Canada; and Society of Obstetricians and Gynaecologists of Canada

Source(s) of Funding

American Society of Colposcopy and Cervical Pathology

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Wright TC Jr, Cox JT, Massad LS, Carlson J, Twiggs LB, Wilkinson EJ. 2001 consensus guidelines for the management of women with cervical intraepithelial neoplasia. Am J Obstet Gynecol 2003 Jul;189(1):295-304.

The guideline was reaffirmed for currency by the developer in 2011.

Guideline Availability

Electronic copies: Available from the American Society of Colposcopy and Cervical Pathology Web site .

Print copies: Available from the American Society of Colposcopy and Cervical Pathology, 20 West Washington St., Suite 1, Hagerstown, MD 21740.

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This summary was prepared by ECRI on February 22, 2004. The information was verified by the guideline developer on February 24, 2004. This summary was updated by ECRI Institute on April 8, 2009. The updated information was verified by the guideline developer on May 29, 2009. The currency of the guideline was reaffirmed by the developer in 2011 and updated by ECRI Institute on January 31, 2012.

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